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Regulatory Directive DIR2010-03

Reassessment of Note to the Canadian Association of Pest Control Officials C94-05: *Proposed Scheduling of 65 Percent Formic Acid for the Detection and Control of Honey Bee Mites*

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Health Canada's Pest Management Regulatory Agency (PMRA) has conducted a reassessment of its Note to Canadian Association of Pest Control Officials (CAPCO) C94-05: *Proposed Scheduling of 65 Percent Formic Acid for the Detection and Control of Honey Bee Mites*.

Background

Formic acid is a naturally-occurring substance found in animals (e.g., venom of ants and bees), and in plants (e.g., stinging nettles). Synthetic formic acid is used world-wide for a variety of commercial uses, such as a preservative and antibacterial agent in livestock feed, a chemical intermediate in the production of various pharmaceuticals, in the tanning process for leather, and as an ingredient in commercial cleaning products.

Note to CAPCO C94-05 was published on March 30, 1994. Since the publication of Note to CAPCO C94-05, a new *Pest Control Products Act* and Regulations have been brought into force and the previously proposed scheduling of formic acid is no longer consistent with current regulatory standards, processes, and practices.

On June 4, 2009, the PMRA published Regulatory Proposal PRO2009-01, *Reassessment of Note to the Canadian Association of Pest Control Officials C94-05: Proposed Scheduling of 65 Percent Formic Acid for the Detection and Control of Honey Bee Mites*. The PMRA received 123 written responses from stakeholders, including commercial and hobby beekeepers, industry, provincial and national beekeeping organisations, scientists, and provincial government apiculturists. Many commented that liquid formic acid is essential to integrated pest management of varroa mites in Canada, and that some beekeepers rely solely on formic acid for mite control. It was also clear that users want to maintain flexibility in methods by which formic acid can be applied. In consideration of these comments, the PMRA has made the following regulatory decision regarding Note to CAPCO C94-05.

Revocation of Note to the Canadian Association of Pest Control Officials C94-05

Note to CAPCO C94-05 will be revoked on March 2, 2011.

- As Note to CAPCO C94-05 is limited in scope to applications of 65% formic acid solution in water, this regulatory decision is limited to products which are only formulated with formic acid and water, with a final application concentration of 65% formic acid in water.
- As an interim measure, if submissions for registration of 65% liquid formic acid are received by March 2, 2011, use of 65% liquid formic acid according to the proposed label(s) may be permitted if the use directions raise no concerns until the completion of the full review of these submissions.
- Any uses of 65% liquid formic acid which are not covered by the label(s) proposed for registration will not be permitted after March 2, 2011.
- Proposed label application methods can be generic (e.g., application rate, method, frequency, and timing) rather than specific (e.g., directions limited to a specific applicator device).

- As Note to CAPCO C94-05 specifically prohibits applications of formic acid during honey flow, applications of formic acid while honey supers are present on the hive are not permitted under this interim measure. Full evaluation and registration of use during honey flow is required for this use to be permitted.
- Should no application for the registration of 65% liquid formic acid be submitted to the PMRA by March 2, 2011, all unregistered uses of formic acid will not be permitted as of that date.

It is recommended that applicants request a presubmission consultation with the PMRA prior to submitting an application for registration in order to clarify the information and data required to support registration. Data requirements will be minimal, and will include a product label, a statement of product specification form, a use site description, and value information.